REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 58-83 are pending after entry of the amendments set forth herein.

Claims 58-80 were examined. Claims 58-80 were rejected. No claims were allowed.

Claim 1 is amended to insert the "an" in between the words "comprises" and exogenous". The new claims find support in the specification and claims as originally filed, specifically in claim 10 and line 21 page 5 to line 24 page 6 and page 38 line 20-page 41, line 4. No new matter has been added by this amendment.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Request for Examiner Interview

In the event the following arguments are not persuasive, and any rejections are to be maintained, Applicants request an interview with the Examiner. The Examiner is invited to telephone the undersigned, or Carol Francis, at the phone number provided below.

New claim 81

The Examiner's attention is respectfully drawn to new claim 81. The subject matter encompassed by new claim 81, like claims 58-80, corresponds to the subject matter of claim group II, as set forth in the Restriction Requirement of March 30, 1998. Claim 81 is a rephrased version of claim 10, as originally filed.

Claim objections

Claim 58 is objected to because it appears to missing the word "an" between the words "comprises" and "exogenous".

Claim 58, as amended, recites "...comprising *an* exogenous...", and, as such, this objection is believed to be moot.

Withdrawal of this rejection is respectfully requested.

Rejection Under §101 and §112, ¶1 (Enablement based on lack of utility)

Claims 58-80 were rejected under 35 U.S.C. §101 on the grounds that the claimed subject matter is not supported by a specific and substantial utility, and further rejected for not being supported by an enabling disclosure under 35 U.S.C. §112, ¶1 in view of this asserted lack of utility. This rejection is respectfully traversed.

The claims are directed towards cellular screening assays. As such, the subject matter of the claims represents a research tool that enables researches to investigate various biological problems (e.g., to identify compounds that can cause or reduce a cellular phenotype, such as cancer cell growth, cell susceptibility to a virus, or antibiotic sensitivity, *etc.*). The Examiner appears to argue that there is no link between a cell with an altered phenotype and a desirable compound, and, accordingly, there no specific or substantial utility for the claimed assays. In making the rejection, the Examiner states "applicants provide an invitation to experiment .....to find some compound with any number of possible utilities".

With regard to research tools, the he MPEP is very instructive. Specifically at MPEP § 2107.01, Part I, the MPEP states:

> *Research Tools*
>
> Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific and substantial utility based on the setting in which the invention is to be used. One example is inventions to be used in a research or laboratory setting. Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact "useful" in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as "research tool," "intermediate" or "for research purposes" are not helpful in determining if an applicant has identified a specific and substantial utility for the invention.

The MPEP therefore dictates that "screening assays, and nucleotide sequence techniques have a clear, specific and unquestionable utility". A link between a cell with an altered phenotype and a

desirable compound does not appear to be necessary, according to the MPEP, for a screening to be useful. Such methods are intrinsically useful for analyzing compounds.

Since the instant claims are directed to screening assays, and the MPEP states, in no uncertain words, that screening assays have a "clear, specific and unquestionable utility", the Applicants respectfully submit that the subject matter of the instant claims, must, too, have a clear, specific and unquestionable utility.

The inventive concept set forth in the instant application is quite simple: a molecular scaffold can be used to bring together enzymes in novel combinations in order to facilitate discovery, e.g., the discovery of drugs. As eluded to in the section of the MPEP cited above, the Office should not confuse *breadth* of utility with a lack of *specific* utility. In other words, an invention which has many applications in a variety of different fields should not be characterized as having no specific use. The present invention, by having many broad utilities, clearly has a use.

Since the subject matter of the instant claims has a clear, specific and unquestionable utility, withdrawal of the rejection of claims 58-80 under 35 U.S.C. §101 and under 35 U.S.C. §112, ¶1, is respectfully requested.

Rejection Under §112, ¶1 – Written Description

Claims 58-80 were again rejected on the grounds that the specification does not provide an adequate disclosure under 35 U.S.C. §112, ¶1. Specifically, the Office Action asserts that the Applicants were not in possession of the full scope of the claimed method at the time of filing because the Applicants were neither in possession of the components required to perform the claimed method, nor of the method for performing the claimed subject matter. This rejection is respectfully traversed.

The inventive concept set forth in the instant application is quite simple: a molecular scaffold can be used to bring together enzymes in novel combinations in order to facilitate discovery, e.g., the discovery of drugs. Once understood, many embodiments of the invention, e.g., which enzymes to use, etc., would become apparent to one of skill in the art without any further description. Since the inventive concept is described in great detail in the instant specification, the written description requirement has been met.

The components required to perform the claimed method are as follows: a nucleic acid encoding an exogenous scaffold, and nucleic acids encoding enzymes with exogenous binding sites that bind to the exogenous scaffold.

The Applicants respectfully submit that the specification provides sufficient detail of the claimed methods to satisfy the written description requirement. Scaffolds are described throughout the specification, particularly on page 7, with exogenous scaffolds being specifically described on page 13. Scaffolds with binding sites are described on pages 13-14, as are enzymes suitable for use in the claimed methods. The specification further describes libraries of scaffolds and enzymes (page 16, lines 5-14). After introducing these enzymes into suitable host cells, (pages 24-26 and page 32), the specification describes screening the cells. (pages 32-33). Specific embodiments of detectable phenotypes and screens are provided throughout the specification, for example on page 36. A summary of the claimed methods are found on pages 3-4, and, further, Figures 1, 2, 3, 4 and 5B, depict specific scaffold-enzyme combinations useful in the claimed methods.

Upon reading the instant specification, particularly at the positions indicated in the previous paragraph, one of skill in the art would understand that the specification adequately describes the claimed invention, and, as such, the claimed invention must have been in the inventors' possession at the time of filing.

In fact, with respect to the Figures, the Synopsis of Application of the Written Description Guidelines, as published to the world wide website of the U.S. Patent and Trademark Office on March 1, 2000, the decision tree shown on pages 8 indicates that the written description requirement is met if a clear depiction of the claimed invention or disclosed species is provided in drawings. Since several specific embodiments of the claimed invention are shown in Figures 1, 2, 3, 4 and 5B, by the standards set forth in the Synopsis, the written description requirement has been met.

The Applicants respectfully submit that the foregoing discussion adequately addresses this rejection. Withdrawal of this rejection is respectfully requested.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number RIGL-014.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

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